

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Filial and Child-Therapist play therapy on Attention and Hyperactivity of Children with ADHD

#### Protocol summary

##### Summary

The purpose of this study is comparison of filial and child-therapist play therapy on attention and hyperactivity of children with ADHD. Play is known as essential requirements for human (child). For children, play, same as food and water, is essential for survival, and also is one of important determinants of health and wellbeing. Meaningful games can severely affect human health and therefore the absence of these games can have destroying consequences to follow. Play is considered as a practical or actual tool for organizing time, place, and materials, patterns, habits and roles will develop through play. Children with ADHD, may make a lot of efforts to be successful in school, which can negatively affect their educational activities, for example it can disrupt their social activities in maintaining positive relationship with peers or may damage family relationships. Attention deficit disorder with hyperactivity is a childhood inherited chronic disorder of neural development. It is known by stable and recurring patterns of attention deficit, impulsivity and hyperactivity characteristics, which is inconsistent with developmental level of child. Play therapy is a method to help affected children for confronting with problems. This method is used as a tool for communication between child and therapist. This method is based on a fundamental assumption that play is a process by which child at first separate "me" from "not-me" and connects with world beyond self. Children communicate with their environment through play. At this study attempts are made to introduce play therapy as an effective method in treatment fields of children, and moreover to compare effectiveness of child-family method with child-therapist method with each other and to report their effectiveness on children with ADHD. This is an experimental study, the target population is children with ADHD, aged 6 to 12 years old, and who were referred to clinical centers of IRAN University of Medical Sciences. Sampling is random, by the way of randomly permuted blocks in available population.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013111615416N1**

Registration date: **2015-06-22, 1394/04/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-22, 1394/04/01

##### Registrant information

##### Name

Hooshang Mirzaie

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2286 5765

##### Email address

h-mirzaie@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2014-02-09, 1392/11/20

##### Expected recruitment end date

2014-03-11, 1392/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of Filial and Child-Therapist play therapy on Attention and Hyperactivity of Children with ADHD

## Public title

The Effects of Play Therapy on children with ADHD

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1 - Diagnosis of Attention Deficit - Hyperactivity by a psychiatrist. 2 - Age between 6 to 12 years old. 3 - Parent's willingness to participate in research and educational group sessions and the ability to record meetings. 4 - At least high school levels of education for parents. 5 - Lack of mental retardation. 6 - Accepting filming sessions (for children - the therapist and the child - parent), by legal guardian. 7 - Make the necessary scale score CSI-IV. 8 - Absence of comorbid disorders (LD, ODD, ...). Exclusion criteria: 1 - There are significant problems with physical, sensory or motor. 2 - There are obvious signs of psychosis in children. 3 - Having certain diseases or disorders (autism, Down syndrome, genetic disorders, etc.). 4 - Significant history of drug abuse, child or parent. 5 - History of seizures and related drugs. 6 - Lack of parental consent to participate in the study or to continue. 7 - Parents suffering mental illness.

## Age

From **6 years** old to **12 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **51**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Comparison of two methods of play therapy and their effects on children with ADHD

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences and Health

Services

#### Street address

Tehran University of Medical Sciences, Keshavarz Blv.

#### City

Tehran

#### Postal code

#### Approval date

2013-11-04, 1392/08/13

#### Ethics committee reference number

1679/130/92/3

## Health conditions studied

### 1

#### Description of health condition studied

Attention Deficit/Hyperactivity Disorder in Children

#### ICD-10 code

F90.0

#### ICD-10 code description

Disturbance of activity and attention

## Primary outcomes

### 1

#### Description

Attention deficit and Hyperactivity

#### Timepoint

Three Months After Intervention

#### Method of measurement

Child Symptom Inventory-4 (CSI-4) and Test of Everyday Attention for Children

## Secondary outcomes

### 1

#### Description

Parenting Stress

#### Timepoint

Three months After Intervention

#### Method of measurement

Parenting Stress Index (PSI)

## Intervention groups

### 1

#### Description

Filial Therapy Intervention. Filial therapy is a short-term treatment approach which combines play therapy with family therapy. Therapist trains family and monitors their activities. Parents conduct child-centered play therapy sessions with their children. Most of these meetings at home without direct supervision of a therapist.

#### Category

Rehabilitation

## 2

### Description

Adlerian Play Therapy Intervention. Child-centered play therapy (Adlerian) was done in a fully equipped play therapy center (at a specific time and place), which was equipped by variety of toys. This group received 30 sessions child-therapist intervention (45 minutes to 1 hour for 10 weeks, 3 days per week).

### Category

Rehabilitation

## 3

### Description

Without Intervention

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Occupational Therapy Clinic, Rehabilitation School of Iran University of Medical Science

##### Full name of responsible person

Prof. Asoon Hasani Mehraban

##### Street address

Rehabilitation School of Iran University of Medical Science, Modar Square, Mirdamad st.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rehabilitation School of Iran University of Medical Sciences

##### Full name of responsible person

Prof. Mojtaba Kamyab

##### Street address

Teharn, Mirdamad avenue, Madar square, Shahid Shah-Nazari street

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Rehabilitation School of Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Hooshang Mirzaie

#### Position

PhD of Occupational Therapy

#### Other areas of specialty/work

#### Street address

Iran University of Medical Sciences, Hemmat high way

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#### Email

hooshang\_mirzaie@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

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Iran University of Medical Sciences

#### Full name of responsible person

Hooshang Mirzaie

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## Person responsible for updating data

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Iran University of Medical Sciences

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#### Position

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*